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Helmut Christian Eder

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CONNOLLY BOVE LODGE & HUTZ LLP

1875 EYE STREET, N.W.

SUITE 1100

WASHINGTON, DC 20036

EXAMINER

CHAN, RICHARD

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/526,492	<b>Applicant(s)</b> EDER ET AL.	
	<b>Examiner</b> RICHARD CHAN	<b>Art Unit</b> 2618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed 1/09/08 have been fully considered but they are not persuasive.

With respect to applicant's arguments regarding independent claim 20, the applicant submits that the Kennedy reference does not specifically disclose

an evoked neural response measuring device comprising: ***a first implanted subsystem configured to be positioned proximate to at least one desired portion of an auditory nerve to provide stimulation*** to the auditory nerve, and further configured to successively detect with electronics unit an evoked neural response of the auditory nerve to said stimulation thereby obtaining a plurality of discrete values collectively representing an ***unsaturated, high gain amplified version of the evoked neural response*** of the auditory nerve;

The examiner respectfully disagrees with the applicant's submission. First, in regards to the first assertion "***a first implanted subsystem configured to be positioned proximate to at least one desired portion of an auditory nerve to provide stimulation***" is not found in the Kennedy reference, the examiner points the applicant to the Kennedy reference, specifically (Col.6 line 58-61) wherein reference number 215 represents an output stimulator, which is an electromechanical output transducer, for producing mechanical vibrations that are coupled to stapes 50 or other suitable auditory elements in order to assist hearing.

With respect to the applicant's second assertion that the Kennedy reference lacks the teaching of "***unsaturated, high gain amplified version of the evoked neural response***"

The examiner points the applicant specifically to (Col.7 Line 38-44) wherein the Kennedy reference specifically discloses an EEG device 300, which is meant to successively detect brain waves, includes a differential amplifier for amplification of the received brain waves.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 20 –38 are rejected under 35 U.S.C. 102(b) as being anticipated by Kennedy (US 5,999,856).

Regarding claim 20, Kennedy discloses an evoked neural response measuring device comprising:

a first implanted subsystem 215 configured to be positioned proximate to at least one desired portion of an auditory nerve to provide stimulation to the auditory nerve 50 (Col.6 line 58-61), and further configured to successively detect with electronics unit 225 an evoked neural response of the auditory nerve to said stimulation thereby obtaining a plurality of discrete values collectively representing an unsaturated, high gain amplified version of the evoked neural response of the auditory nerve; (Col.7 Line 38-44) and (Col.6 line 43-61)

and a second subsystem configured to reconstruct said plurality of discrete values into a continuous waveform. (Col.7 line 1-56)

Regarding claim 21, Kennedy discloses the device of claim 20, wherein said first subsystem comprises:

an electrode array 310A-C configured to stimulate said at least one desired section of the auditory nerve and to detect said discrete values (Calibration unit 240 enables discrete detection of brain signals Col.8 line 22-42) of said response of the desired auditory nerve section at successive time intervals; (Col.7 line 32-38)

a high gain amplifier (Differential Amplifier) having a reference voltage input configured to be set to a first of said detected discrete values of said evoked response at a first time, and a signal input configured to be set to second of said detected discrete values of said evoked response at a second time subsequent to said first time, and wherein said amplifier is configured to amplify the difference in said discrete values of said evoked response between said first time and said second time. (Col.7 line 38-51)

Regarding claim 22, Kennedy discloses the device of claim 20, wherein said second subsystem comprises: an integrator 330 configured to reconstruct said plurality of detected discrete values into a continuous waveform. (Averaging) (Col.7 line 45-48)

Regarding claim 23, Kennedy discloses the device of claim 21, wherein said reference voltage (Calibration output signal provided by electronics unit 225) input is

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configured to be set to said first of said detected discrete values of said evoked response at the commencement of each said time interval, and wherein said signal input (signal being delivered by output stimulator 215) is configured to be set to said second of said detected discrete values of said evoked response at end of each said interval. (Col.10 line 47-67)

Regarding claim 24, Kennedy discloses the device of claim 21, wherein said first subsystem further comprises: a sample-and-hold circuit step 800 having an input from said electrode array configured to set the reference voltage of said amplifier equal to a present value of the evoked response at the commencement of each said interval. (Col.10 line 47-67)

Regarding claim 25, Kennedy discloses the method of measurement of an evoked neural response in a cochlear implant comprising:

stimulating a desired section of an auditory nerve to elicit an evoked neural response 50, (Col.6 line 43-61) via a first implanted subsystem positioned proximate to the section of auditory nerve (Col.6 line 58-61);

successively detecting the evoked neural response of the auditory nerve at a plurality of intervals via the first implanted subsystem to obtain a plurality of discrete values collectively representing an unsaturated, high gain amplified version of the evoked neural response; and reconstructing said plurality of discrete values into a continuous waveform. (Col.7 line 1-56)

Regarding claim 26, Kennedy discloses the method of claim 25, wherein sampling the evoked neural response at the plurality of intervals comprises: successively altering a reference voltage of a high gain amplifier at the commencement of each sample said interval such that each discrete value equals an amplified form of the voltage change in the evoked neural response over said interval. (Col.10 line 47-67)

Regarding claim 27, Kennedy discloses the method of claim 26, wherein each altering of said reference voltage comprises: setting said reference voltage equal to a present value of the evoked neural response at the commencement of each interval. (Col.10 line 47-67)

Regarding claim 28, Kennedy discloses the method of claim 25, wherein each said sampling comprises:

obtaining from a sensor at a first time a first value representing the evoked neural response; (Col.7 line 30-37)

setting a reference voltage of a high gain amplifier 300 equal to said first value of the evoked neural response;

obtaining from said sensor at a second time subsequent said first time a second value representing the evoked neural response;

setting a signal input of said high gain amplifier equal to said second value of the evoked neural response;

amplifying with said high gain amplifier the voltage difference between the said first and said second values of the evoked neural response. (Col.7 line 38-44)

Regarding claim 29, Kennedy discloses the method of claim 28, wherein setting the reference voltage of the high gain amplifier equal to said first value comprises: setting the reference voltage of the high gain amplifier equal to the present value of the evoked neural response at the commencement of each said interval. (Col.10 line 47-67)

Regarding claim 30, Kennedy discloses the method of claim 25, wherein reconstructing said plurality of discrete values into the continuous waveform comprises: integrating said plurality of discrete values to obtain said continuous waveform. (Averaging) (Col.7 line 45-48)

Regarding claim 31, Kennedy discloses the method of claim 28, wherein obtaining said first and second values comprises: utilizing one or more electrodes of an electrode array of a cochlear implant to obtain said values. (Col.7 line 1-56)

Regarding claim 32, Kennedy discloses the device for measuring of an evoked neural response in a cochlear implant comprising:

Means for simulating a desired of an auditory nerve to elicit an evoked neural response and for sampling the evoked neural response 50 (Col.6 line 58-61), (Col.6 line



43-61) a plurality of intervals to obtain a plurality of discrete values collectively representing an unsaturated, high gain amplified version of the evoked neural response; (Col.7 line 1-56) and means for reconstructing said plurality of discrete values into a continuous waveform. (Averaging) (Col.7 line 45-48)

Regarding claim 33, Kennedy discloses the device of claim 32, wherein said means for sampling the evoked neural response at the plurality of intervals includes: means for successively altering a reference voltage of a high gain amplifier at the commencement of each said interval such that each discrete value equals an amplified form of the voltage change in the evoked neural response over said interval. (Col.10 line 47-67)

Regarding claim 34, Kennedy discloses the device of claim 33, wherein each means for altering said reference voltage comprises: means for setting said reference voltage equal to a present value of the evoked neural response. (Col.10 line 47-67)

Regarding claim 35, Kennedy discloses the device of claim 32, wherein each said means for sampling comprises: means for obtaining from a sensor at a first time a first value representing the evoked neural response 50, (Col.6 line 43-61); means for setting a reference voltage of a high gain amplifier equal to said first value of the evoked neural response; means for obtaining from said sensor at a second time subsequent said first time a second value representing the evoked neural response; (Col.7 line 1-

56) means for setting a signal input of said high gain amplifier equal to said second value of the evoked neural response; means for amplifying with said high gain amplifier the voltage difference between the said first and said second values of the evoked neural response. (Col.10 line 47-67)

Regarding claim 36, Kennedy discloses the device of claim 35, wherein said means for setting the reference voltage of the high gain amplifier equal to said first value comprises: means for setting the reference voltage of the high gain amplifier equal to the present value of the evoked neural response at the commencement of each sample interval. (Col.10 line 47-67)

Regarding claim 37, Kennedy discloses the device of claim 32 wherein said means for reconstructing said plurality of discrete values into a continuous waveform comprises: means for integrating said plurality of discrete values to obtain said continuous waveform representing an amplified form of said evoked neural response. (Averaging) (Col.7 line 45-48)

Regarding claim 38, Kennedy discloses the device of claim 35, wherein said means for obtaining said first and second values comprises: means for utilizing one or more electrodes of an electrode array of a cochlear implant to obtain said values. (Col.7 line 1-56)

***Conclusion***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The Nygard reference (US 5,758,651) discloses a Telemetry system and appartus.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Chan whose telephone number is (571) 272-0570. The examiner can normally be reached on Mon - Fri (9AM - 5PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nay Maung can be reached on (571)272-7882. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Richard Chan/

Examiner, Art Unit 2618